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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,933	09/14/2005	Shangguan Tong	TRA-027.01	1561

25181 7590 12/28/2006

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EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	PAPER NUMBER
1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,933	TONG ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-168 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-168 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s)74-141, and 144-146, drawn to a method for preparing liposomes containing a nucleic acid encapsulated therein comprising the following steps: mixing a gel or a liquid containing gel particles with aqueous medium Z1 to directly form liposomes, wherein said gel or liquid containing gel particles comprises at least one liposome-forming lipid, at least one fusogenic lipid, a water-miscible organic solvent and the at least one nucleic acid, wherein the at least one liposome-forming lipid and the at least one fusogenic lipid are the same or different.

Group 2, claim(s) 74-141, and 144-146, drawn to a method for preparing liposomes containing a nucleic acid encapsulated therein comprising the following steps: (i) mixing a gel or a liquid containing gel particles with aqueous medium Z1 to form a curd or curdy substance, wherein said gel or liquid containing gel particles comprises at least one liposome-forming lipid, at least one fusogenic lipid, a water-miscible organic solvent and the at least one nucleic acid, wherein the at least one liposome-forming lipid and the at least one fusogenic lipid are the same or different; and (ii) mixing the curd or curdy substance with aqueous medium Z2 to directly form the liposomes.

Group 3, claims 74-141, and 144-146, drawn to a method for preparing liposomes containing a nucleic acid encapsulated therein comprising the following steps: (i) cooling a gel or a liquid containing gel particles to form a waxy substance, wherein said gel or liquid containing gel particles comprises at least one liposome-forming lipid, at least one fusogenic lipid, a water-miscible organic solvent and the at least one nucleic acid; and (ii) mixing the waxy substance with aqueous medium Z1 to directly form the liposomes containing the at least one nucleic acid encapsulated therein.

Group 4, claims 74-141, and 144-146, drawn to a method for preparing liposomes containing a nucleic acid encapsulated therein comprising the following steps: mixing a gel or a liquid containing gel particles with aqueous medium Z1 and the at least one nucleic acid to directly form the liposomes containing the at least one nucleic acid encapsulated therein, wherein said gel or liquid containing gel particles comprises at

least one liposome-forming lipid, at least one fusogenic lipid and a water-miscible organic solvent.

Group 5, claims 74-141, and 144-146, drawn to a method for preparing liposomes containing a nucleic acid encapsulated therein comprising the following steps: (i) mixing a gel or a liquid containing gel particles with aqueous medium Z1 and the at least one nucleic acid to form a curd or curdy substance, wherein said gel or liquid containing gel particles comprises at least one liposome-forming lipid, at least one fusogenic lipid and a water-miscible organic solvent; and (ii) mixing the curd or curdy substance with aqueous medium Z2 to directly form the liposomes containing the at least one nucleic acid encapsulated therein.

Group 6, claims 74-141, and 144-146, drawn to a method for preparing liposomes containing a nucleic acid encapsulated therein comprising the following steps: (i) mixing a gel or a liquid containing gel particles with aqueous medium Z1 to form a curd or curdy substance, wherein said gel or liquid containing gel particles comprises at least one liposome-forming lipid, at least one fusogenic lipid and a water-miscible organic solvent; and (ii) mixing the curd or curdy substance with aqueous medium Z2 and the at least one nucleic acid to directly form the liposomes containing the at least one nucleic acid encapsulated therein.

Group 7, claims 74-141, and 144-146, drawn to a method for preparing liposomes containing a nucleic acid encapsulated therein comprising the following steps: (i) cooling a gel or a liquid containing gel particles to form a waxy substance, wherein said gel or liquid containing gel particles comprises at least one liposome-forming lipid, at least one fusogenic lipid, a water-miscible organic solvent and the at least one nucleic acid; and (ii) mixing the waxy substance with aqueous medium Z1 to directly form the liposomes containing the at least one nucleic acid encapsulated therein.

Group 8, claims 74-141, and 144-146, drawn to a method for preparing liposomes containing a nucleic acid encapsulated therein comprising the following steps: (i) cooling a gel or a liquid containing gel particles to form a waxy substance, wherein said gel or liquid containing gel particles comprises at least one liposome-forming lipid, at least one fusogenic lipid and a water-miscible organic solvent; and (ii) mixing the waxy substance with aqueous medium Z1 and the at least one nucleic acid to directly form the liposomes containing the at least one nucleic acid encapsulated therein.

Note that claims to compositions made by the methods of groups 1-8 (claims 1-73 and 153-168), and claims to a first method of using these liposomes (claims 147-152), will be examined together with the elected group, to the extent that they are defined by the elected group.

After election of a group as listed above, a further election pertaining to claims 142 and 143 is required as follows. These claims disclose 9 different methods of preparing the

gel, or the liquid containing gel particles, required for the 8 groups listed above as follows.

Claim 142 discloses 3 different methods for preparing the gel or the liquid containing gel particles, i.e. method 142 I(a)(aa), method 142 I(a)(bb) and method 142 I(b).

Method 142 I(a)(aa) is: mixing at least one liposome-forming lipid, the at least one fusogenic lipid, the at least one nucleic acid and a water-miscible organic solvent to form a mixture; and then mixing the mixture of the preceding step with aqueous medium Y and optionally the at least one nucleic acid to form the gel or liquid containing gel particles.

Method 142 I(a)(bb) is (i) dissolving at least one liposome-forming lipid and the at least one fusogenic lipid in the water-miscible organic solvent to form an organic solution; (ii) dissolving the at least one nucleic acid in aqueous medium X to form an aqueous solution; and (iii) mixing the organic solution and aqueous solution to form a mixture, and then mixing the mixture of the preceding step with aqueous medium Y and optionally the at least one nucleic acid to form the gel or liquid containing gel particles.

Method 142 I(b) is mixing at least one liposome-forming lipid, the at least one fusogenic lipid and the water-miscible organic solvent to form a mixture; and thereafter mixing the mixture of step (I)(b) with the at least one nucleic acid and aqueous medium Y to form the gel or liquid containing gel particles, wherein aqueous media X and Y are the same or different.

Claim 143 discloses 6 more methods for preparing the gel or the liquid containing gel particles which are unrelated to each other or to the methods of claim 142. These methods are methods 143 (a)-(f) respectively, as follows

(a) (i) providing liposomes comprising the at least one liposome-forming lipid and the at least one fusogenic lipid, wherein the liposomes are prepared by a method other than the instant method; and (ii) mixing the liposomes of step (I)(a)(i) with the at least one nucleic acid, and mixing the product of the previous with aqueous medium U and the water-miscible organic solvent to form the gel or the liquid containing gel particles, wherein aqueous media U and V are the same or different.

(b) (i) providing liposomes comprising the at least one liposome-forming lipid and the at least one fusogenic lipid in aqueous medium U, wherein the liposomes are prepared by a method other than the instant method; and (ii) mixing the liposomes of step (I)(b)(i) with the at least one nucleic acid; and mixing the product of the previous step with the water-miscible organic solvent to form the gel or the liquid containing gel particles:

(c) (i) providing liposomes comprising the at least one liposome-forming lipid and the at least one fusogenic lipid, wherein the liposomes are prepared by a method other than the instant method; and (ii) mixing the liposomes of step (I)(c)(i) with aqueous medium U and the at least one nucleic acid, and mixing the product of the previous step

with the water-miscible organic solvent to form the gel or the liquid containing gel particles.

(d) (i) providing liposomes comprising the at least one liposome-forming lipid and the at least one fusogenic lipid in aqueous medium U, wherein the liposomes are prepared by a method other than the instant method; and (ii) mixing the liposomes of step (l)(d)(i) with aqueous medium U and the at least one nucleic acid, and mixing the product of the previous step with the water-miscible organic solvent to form the gel or the liquid containing gel particles.

(e) forming liposomes comprising the at least one liposome-forming lipid and the at least one fusogenic lipid in the presence of the at least one nucleic acid by a method other than the instant method, and mixing the product of the previous with aqueous medium U and the water-miscible organic solvent to form the gel or the liquid containing gel particles, wherein aqueous media U and V are the same or different.

(f) forming liposomes comprising the at least one liposome-forming lipid and the at least one fusogenic lipid in aqueous medium U in the presence of the at least one nucleic acid by a method other than the instant method; and thereafter and mixing the product of the previous step with the water-miscible organic solvent to form the gel or the liquid containing gel particles.

Upon election of one of these inventions, claim 142, or 143, will be examined, together with claims of one of gorups 1-8, to the extent it is defined by the elected group.

The inventions listed as Groups 1-8 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature linking the various methods is simply a method of "preparing liposomes containing a nucleic acid" as recited in the preamble. The eight methods that follow all comprise different stpes and contain no unifying technical feature. Methods of making liposomes containing nucleic acids were well known in the art prior to the invention (see e.g. Eppstein et al (US Patent 4,897,355) or Papahadjopolous et al (US Patent 4,235,871), of record), so there is no special technical feature linking the various inventions.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Richard Schnizer, Ph.D.
Primary Examiner
Art Unit 1635